

Appl. No.: 10/645,863

Response to Office Communication dated April 19, 2005

**Amendments to the Claims:**

This listing of the claims replaces all prior versions and listings of claims in the instant application:

**Listing of Claims:**

1. (Currently Amended) A business method comprising:
  - a) collecting more than 10 case samples representing a clinical phenotypic state and more than 10 control samples representing patients without said clinical phenotypic state;
  - b) using electrophoresis followed by a mass spectrometry platform system to obtain mass spectral components in said case samples and in said control samples without regard to a specific identity of at least some of said mass spectral components;
  - c) identifying in a computer system representative patterns of markers that distinguish datasets from case samples and control samples wherein said patterns contain more than 15 markers that are represented on output of said mass spectrometer, but the specific identity of a plurality of said more than 15 markers is not known;
  - d) marketing diagnostic products that use said representative patterns wherein said diagnostic products are marketed with a disposable microfluidics device; and
  - e) from blood samples of patients, in a computer system, identifying the differences in case samples and control samples using said plurality of said more than 15 markers wherein the specific identity of said more than 15 markers is not known.
2. (Canceled).
3. (Previously Presented) The method as recited in claim 1 wherein said products are marketed in a clinical reference laboratory.
4. (Withdrawn) The method as recited in claim 1 wherein said marketing step markets kits.
5. (Withdrawn) The method as recited in claim 3 wherein said kits are FDA approved kits.
6. (Withdrawn) The method as recited in claim 1 wherein said phenotypic state is a drug response phenotype and further comprising the step of collecting a royalty on said drug.
7. (Previously Presented) The method as recited in claim 1 further comprising the step of collecting said samples in collaboration with a collaborator.

Appl. No.: 10/645,863

Response to Office Communication dated April 19, 2005

8. (Original) The method as recited in claim 7 wherein said collaborator is an academic collaborator.

9. (Original) The method as recited in claim 7 wherein said collaborator is a pharmaceutical company.

10. (Original) The method as recited in claim 9 wherein said pharmaceutical company collects said samples in a clinical trial.

11. (Withdrawn) The method as recited in claim 10 wherein said patterns are used to segregate a drug response phenotype.

12. (Withdrawn) The method as recited in claim 11 further comprising the step of collecting royalties on said drug.

13. (Withdrawn) The method as recited in claim 11 wherein the step of marketing diagnostic products is performed by the same company as the company performing the identifying step.

14. (Previously Presented) The method as recited in claim 1 wherein data from one of said samples are being processed computationally while another of said samples are in said mass spectrometry platform.

15. (Original) The method as recited in claim 1 wherein said markers are polypeptides.

16. (Canceled)

17. (Currently Amended) The method as recited in claim 15 wherein said patterns contain more than 30 polypeptides that are represented on output of said mass spectrometer, but the specific identity ~~of at least some~~ of said more than 30 polypeptides is not known.

18. (Currently Amended) The method as recited in claim 15 wherein said patterns contain more than 50 polypeptides that are represented on output of said mass spectrometer, but the specific identity ~~of at least some~~ of said more than 50 polypeptides is not known.

19. (Currently Amended) The method as recited in claim 15 wherein said patterns contain more than 100 polypeptides that are represented on output of said mass spectrometer, but the specific identity ~~of at least some~~ of said more than 100 polypeptides is not known.

20. (Currently Amended) The method as recited in claim 15 wherein said samples contain more than 1000 polypeptides that are represented on output of said mass

Appl. No.: 10/645,863

Response to Office Communication dated April 19, 2005

spectrometer, but the specific identity of at least some of said more than 1000 polypeptides is not known.

21. (Withdrawn) The method as recited in claim 1 wherein said marketing step markets a mass spectrometry system used to identify said representative states in patient samples.

22. (Previously Presented) The method as recited in claim 1 wherein more than 50 of said cases samples and 50 of said control samples are used.

23. (Previously Presented) The method as recited in claim 1 wherein more than 100 of said case samples and 100 of said control samples are used.

24. (Previously Presented) The method as recited in claim 1 wherein said diagnostic products use said mass spectrometry platform.

25. (Previously Presented) The method as recited in claim 1 wherein said step of using a mass spectrometry platform is preceded by the step of preparing said samples on a microfluidics device.

26. (Original) The method as recited in claim 25 wherein said diagnostic products are marketed with a disposable microfluidics device, said disposable microfluidics device processing diagnostic samples for use in said mass spectrometry platform.

27. (Original) The method as recited in claim 25 wherein said microfluidics device comprises a separations device.

28. (Canceled)

29. (Previously Presented) The method as recited in claim 1 wherein said mass spectrometry platform is a time of flight mass spectrometer.

30. (Previously Presented) The method as recited in claim 1 wherein said mass spectrometer is a Hadamard time of flight mass spectrometer.

31. (Previously Presented) The method as recited in claim 1 wherein said diagnostic products are marketed by a diagnostic partner.

32. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a drug response phenotype.

33. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a drug resistance phenotype.

Appl. No.: 10/645,863

Response to Office Communication dated April 19, 2005

34. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a disease stage phenotype.

35. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a disease recurrence phenotype.

36. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a disease state phenotype.

37. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a treatment selection phenotype.

38. (Previously Presented) The method as recited in claim 1 wherein said phenotype is a disease diagnostic phenotype.

39. (Withdrawn) The method as recited in claim 1 wherein said phenotype is a drug toxicity phenotype.

40. (Withdrawn) The method as recited in claim 1 wherein said phenotype is an adverse drug response phenotype.

41. (Original) The method as recited in claim 25 wherein said microfluidics device comprises an electrospray source.

42. (Previously Presented) The method as recited in claim 1 wherein said samples contain complex mixtures of polypeptides.

43. (Withdrawn) The method as recited in claim 1 wherein revenue is derived from sales of microfluidics devices, mass spectrometers, informatics tools, patterns and/or computer programs for classifying samples and/or from services that provide diagnostic information and/or pattern discovery and/or validation.